



Research Guide: The Federal REgulation of Dietary Supplements

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Research Guide: The Federal Regulation of Dietary Supplements

Heather Hegefeld
May 1999

INTRODUCTION

Of all food- and drug-related legal issues, the regulation of dietary supplements has certainly been at or near the top of the “most controversial” list. The entire regulatory scene was turned inside-out with the enactment of the Dietary Supplement Health and Education Act (DSHEA) in 1994, which dramatically decreased the Food and Drug Administration’s authority to regulate dietary supplements, particularly in the context of dietary supplement labeling. Prior to the enactment of the DSHEA, the FDA was planning to tighten its regulatory hold in the arena of dietary supplements, a position that was summarily reversed following the passage of the DSHEA.

The DSHEA is both loved and hated. The FDA and other public health organizations have expressed and continue to express safety concerns about the decreased amount of regulation of dietary supplements. Other groups, especially those interested in consumer choice, regard the DSHEA as a long overdue bastion of consumer choice and health freedom. As those groups rejoice, however, the FDA continues to propose regulations that will weaken the power of the DSHEA. Most recently, the courts have stepped in and mandated the FDA to clarify its position with regard to the regulation of dietary supplements under the DSHEA. With all of this happening at once, the federal regulation of dietary supplements after the DSHEA is one topic in which many lawyers, scholars, and students are interested. This research guide is designed to help the researcher in the task of wading through all of the relevant materials in this area, as well as to provide the researcher with helpful tips for efficient research.

SCOPE NOTE

This research guide explores the techniques for researching the federal regulation of dietary supplements after the passage of the Dietary Supplement Health and Education Act. As such, it focuses on federal regulation only and does not address any potential overlap between federal and state regulation. Additionally, this research guide is not intended to be a guide to researching the exhaustive history of the federal regulation of dietary supplements. Its narrow focus is on the very latest regulation of dietary supplements after the DSHEA, passed on October 25, 1994 (though I have referred to the topic generically as the regulation of dietary supplements in the guide to make things simpler). Generally, my time focus has been post-1994, however, at times in the guide I have specified that the researcher should check the years prior to 1994 in order to get a feel for the before and after effects of the DSHEA. This research guide does cover a variety of legal resources, including secondary materials, administrative materials, statutory materials, case law and others, as well as non-legal materials that provide a great deal of relevant information. Since the internet is an increasingly important research tool, this guide provides relevant internet website addresses and search tips as well.

Practically, this guide is directed to law students who are interested in researching this issue in the future. Because such an audience most often has unlimited, free access to on-line databases, I have provided all relevant on-line database identifiers and other on-line search information. During the research for this guide, I generally used the disk version of Westlaw and the Internet version of Lexis. The citations I have given to Westlaw databases apply on either version, and I have given the library name and file name for Lexis files

for ease of use on either version as well. Additionally, I have provided some cost-saving tips when applicable for the law student who will eventually become a practitioner concerned with lowering research expenses as much as possible.

Summary of the Top Three Sources

Information about the regulation of dietary supplements after the DSHEA can be found in a countless number of sources. However, some sources stand out as the very best, either because they contain a lot of information themselves or provide links or citations to an enormous amount of information contained in other sources. Together, these sources contain about 90% of the relevant information and should be consulted first.

And the winners are...

(1)

For more information about this website, see pps. 7, 13, and 44 of this Research Guide.

(2)

For a further description of the brief, see p. 51 of this Research Guide.

(3)

For more information about this book, see pps. 15 and 57 of this Research Guide.

Just by using these three sources, the legal researcher can get a good feel for the administrative materials, statutory materials, legislative history, cases, and secondary materials relating to the regulation of dietary supplements. Additionally, the legal researcher can also gain a lot of information about the history of regulation, the development of the DSHEA, the aftermath of the DSHEA, and the latest developments in the regulation of dietary supplements. However, for the legal researcher interested in the more specific sources, I have provided in the rest of this guide more in-depth research advice for all these genres, listed

generally by most important to least important genre.

Statutory Materials

Because the Dietary Supplement Health and Education Act (DSHEA) is an integral part of this research topic, statutory research is essential. Not only will statutory research lead the researcher to the text of relevant statutes, it will also lead to researcher to relevant cases and secondary materials.

Finding Relevant Statutes by Popular Name

If the researcher only knows the name of an act, such as the Dietary Supplement Health and Education Act, there are two research sources that will lead the researcher to the relevant text of the statute. The following print sources are helpful in finding statutory citations from a popular name:

Popular Name Table in the United States Code Annotated
St. Paul, MN: West Publishing
LC Call#: KF62 1927. W45
(located in the last volume of the General Index)

Shepard's Acts and Cases by Popular Name
Colorado Springs, CO: Shepard's/McGraw Hill, Inc.
LC Call#: KF90. S52 (1992)
(Cumulative supplement)

The Popular Name Table of the USCA is also available on Westlaw in the USCA-POP database and on Lexis in the CODES library; USNAME file.

Both sources provide the relevant public law number and Statutes at Large citation, however the entry in the Popular Name Table of the United States Code Annotated also lists the relevant places the Act appears in the United States Code Annotated. I found that feature to be particularly helpful.

The Public Law Number

When statutes are passed, they are given a public law number that represents the Congress (e.g. 104th, 105th, etc.) and the numerical order of passage. For example, the public law number for the DSHEA is P.L. 103-417. By looking at the public law number, the researcher should know that the DSHEA was the 417th public law passed during the 103rd Congress.

By looking at the public law citation, the researcher can see the text of the Act as passed. The advance legislative service for federal statutes is U.S. Code Congressional and Administrative News, which contains public laws arranged chronologically.

U.S. Code Congressional and Administrative News (USCCAN)
St. Paul, MN: West Publishing
LC Call#: KF 48. W45

By using USCAAN, the researcher can cite to the Statutes at Large bound volume of session laws:

Statutes at Large
Washington, DC: Government Printing Office
LC Call#: KF 50.U5

The Statutes at Large cite refers the researcher to the relevant volume and page number of the Statutes at Large. The relevant Statutes at Large citation for the DSHEA is 108 Stat. 4325.

On-line collections of laws passed by Congress by session in public law format can be found in the following databases on Westlaw and Lexis:

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Codes

The official source for federal statutes is the United States Code. However, for legal research purposes, the best sources are the annotated codes.

The following are the two prominent annotated codes in print:

United States Code Annotated (U.S.C.A)
St. Paul, MN: West Publishing
LC Call#: KF62 1927 W.45

United States Code Service (U.S.C.S.)
Charlottesville, VA: Lexis Law Publishing
LC Call#: KF62 1972.L38

The U.S.C.A. and U.S.C.S. are exactly like the U.S.C., with the addition of helpful annotations. Additionally, annotated codes are numbered exactly like the U.S.C., so the researcher can cite to the U.S.C. by using annotated codes. The annotated codes are updated by yearly pocket parts and monthly pamphlet supplements. To begin researching the annotated codes, consult the General Index. For the regulation of dietary supplements, the most relevant index topics in the U.S.C.A. are:

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The most relevant topics in the U.S.C.S. are:

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In addition to their print form, these annotated codes are available on-line as well:

U.S.C.S. – available on Lexis in the GENFED library; USCS file

U.S.C.A. – available on Westlaw in the USCA database

(Searching the on-line General Indices to the U.S.C.A. on Westlaw and the U.S.C.S. on Lexis is particularly useful because they contain links to the annotated codes.)

The researcher should be aware that there are narrower databases available that work as effectively as the combined files, but save research costs. The health care divisions of the annotated codes are searchable on-line and should be consulted first:

Westlaw – FHTH – USCA (searches only health-related titles)

Lexis – HEALTH library; USCS file (searches only health-related titles)

Finally, the Tables Volumes of the annotated codes are useful for the researcher who has a public law or Statutes at Large citation and needs to find where the Act is found in the annotated code. The DSHEA is found in the annotated codes in the following titles and sections:

Title 21 – Food and Drugs

Relevant Sections:

321

331

342

343

343-2

350

350b

Title 42 – Public Health and Welfare

Relevant Sections:

281

287c-11

Because annotated codes on-line are not up-to-date, you must update your research by searching in the public law files for new laws. The US-PL file on Westlaw and GENFED library; PUBLAW file on Lexis contain public laws passed by the current Congress (although the Westlaw database only says it contains documents from the 105th Congress, not the current 106th Congress – be sure to check the scope note). Because these files are generally smaller, a search for “dietary /3 supplement” will not generally over-retrieve. The only relevant public law passed by the current Congress is the Food and Drug Modernization Act, which I have described at the end of this section.

Internet Sources for Federal Statutory Material

The best Internet source for finding federal statutory material is the Thomas homepage at the Library of Congress website. (<http://thomas.loc.gov>) The researcher can search the website by public law number for the current and previous Congress'. In addition to providing the texts of public laws, the Thomas site has useful legislative history information and bill tracking information. These features are fully explained in the Legislative History section of this guide.

Locating Cases and Secondary Material Using Annotated Codes

In order to gain the most case and secondary citations, the researcher should consult both the U.S.C.S. and the U.S.C.A. as well as Shepard's Federal Statute Citations:

Shepard's Federal Statute Citations

Colorado Springs, CO: Shepard's/McGraw Hill, Inc.

LC Call#: KF78.57

Summary of DSHEA

By using all of the above resources, I found that the DSHEA amends the Federal Food, Drug and Cosmetic Act in several important ways. The following list contains some of the major provisions:

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321(ff))

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Additional Regulation of Dietary Supplements Since the Enactment of the DSHEA – The Food and Drug Modernization Act

This major food and drug Act slightly changed the regulation of dietary supplements in the following ways
(*see* 21 U.S.C. §343(r)(2 –3)):

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Administrative Materials

Administrative materials provide a great deal of specific information about the regulation of dietary supplements. Administrative agencies issue rules and regulations that are much more particularized than statutes, and these rules and regulations have the force and effect of law. In addition to their legislative function, agencies produce material pursuant to their judicial and executive functions that could also be helpful for the legal researcher.

The Food and Drug Administration is the relevant administrative agency for this topic. In order to find out more about the FDA, including its location and contact information as well as a summary of its functions, the researcher should consult the:

U.S. Government Manual

Washington, DC: Government Printing Office
1998-1999

LC Call#: REF DESK JK 421.A3

Relevant pps.: 267-268; 279-282

The U.S. Government Manual explains that the Food and Drug Administration is an agency of the Department of Health and Human Services and provides a short summary of the agency's purpose and tasks. The researcher can contact the FDA at the following address:

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-443-1544
<http://www.fda.gov>

The Legislative Function of Agencies

Print Sources

Agencies issue rules and regulations in an order that somewhat parallels the order in which statutes are issued. Agency documents are issued first, number sequentially, followed by looseleaf services. Next, the regulation is published in a register. Registers contain documents from many agencies. Last, final rules and regulations are codified in an administrative code by subject.

For the federal researcher, the Federal Register and Code of Federal Regulations (C.F.R.) should both be searched. The Federal Register should be searched in addition to the C.F.R. for two reasons: (1) to find new regulations that do not change or repeal old regulations, and (2) to find proposed rules and regulations, presidential documents, and notices.

Code of Federal Regulations
Washington, DC: Government Printing Office
LC Call#: KF 70.A3

Federal Register
Washington DC: Government Printing Office

LC Call#: KF 70.A2

To search the C.F.R., the researcher should first consult the topical index:

Index to the C.F.R.
Bethesda, MD: CIS Publishing
LC Call#: KF 70.A34

The CIS Index is much better than the official index, however, its main disadvantage is that it is out of date. The latest edition on the shelf at this time is the 1997 index. I found that the most relevant topic in the index was “dietary supplements – labeling and packaging.” The index will lead the researcher to the most relevant portions of the C.F.R., which I have listed later in this section.

As of May 5, 1999, the C.F.R. is current until April 1, 1998. To update the C.F.R. in print, first consult the latest issue of the List of Sections Affected (LSA) (KF 70.A3). The LSA is current from April 1, 1998 until February 26, 1999. (Be sure the dates of the C.F.R. and LSA line-up.) The LSA is organized by C.F.R. title and will provide information about any changes to the C.F.R. during the time period covered. For example, the LSA indicates that one of the most important sections, 21 C.F.R. §101.36, was revised in the Federal Register for June 5, 1998 at p. 30620. To further update the search, the researcher should consult the Reader's Aid section, CFR Parts Affected During ---- table in the last issue of the Federal Register for each month since the LSA. By way of illustration, I had to consult the last issue of the March Federal Register and the last issue of the April Federal Register to update my search. I found that there were no relevant changes in the last two months.

As I stated above, it may also be important to search the Federal Register. The following index should be consulted:

Federal Register Index
Bethesda, MD: CIS Publishing

LC Call#: KF 70.A2 suppl.

The most relevant topic in the CIS Federal Register Index is "Dietary Supplement Health and Education Act." Because I was interested in all of the proposed regulations, notices, etc, since the DSHEA was enacted, I consulted the indices all the way back to 1994. I have also listed some of the most relevant proposed rules and notices below.

On-line Sources

As is obvious from my description of print sources, searching through books can be a very tedious process. Much of this can be eliminated by using the vast resources on-line.

The best on-line source is the Government Printing Office website at <http://www.access.gpo.gov>. By clicking on the "Publications" option, the user can find the present C.F.R. and the Federal Register going back to 1995 in its *official* version. This website has a lot of really good features, such as the option to search for types of documents in the Federal Register, the option to search only one particular year of the Federal Register, and many more. I found that the best search query for the Federal Register was "dietary supplement health and education' OR DSHEA" used as a keyword search. This search retrieves all regulations, notices, etc. that mention the DSHEA since 1995. The broader term "dietary supplement" must be used to find all relevant entries in the C.F.R.

Lexis and Westlaw also have C.F.R. and Federal Register databases. All of the following files can be found

in the GENFED library on Lexis:

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In the HEALTH library, the CFR file (searches health-related titles, including title 21) and FEDREG file can also be used for a more narrow search. The researcher should be aware, however, that the FEDREG file contains *selected* Federal Register documents.

The following databases on Westlaw are also useful:

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The same search queries that were effective for the GPO site are also very effective in Westlaw and Lexis. I did limit the dates to after 1992 in order to get a feel for the regulations that were in place just prior to the enactment of the DSHEA in October of 1994.

The Most Important Regulations

There are a large number of relevant regulations, proposed regulations, and notices. I have summarized the most important regulations, proposed rules, and notices below and have listed the citations of other relevant documents as well.

The following two notices of proposed rulemaking illustrate the impact that the DSHEA had on federal regulation:

Regulation of Dietary Supplements
Food and Drug Administration
Advance Notice of Proposed Rulemaking
58 F.R. 33690-3370
June 18, 1993
Summary:

In this proposed rule, the FDA expresses concern about the possible safety concerns posed by dietary supplement. It specifically addresses the need for safety and labeling regulations and asserts that it has the power to make such regulations.

Regulation of Dietary Supplements
Food and Drug Administration
Withdrawal of Advance Notice of Proposed Rulemaking
59 F.R. 62644
December 6, 1994

Summary:
This document acknowledges that the DSHEA declared the above notice of proposed rulemaking to be null and void. It illustrates the profound effect of the DSHEA on the FDA's power to regulate dietary supplements.

The following final regulations are the most relevant and most often cited, listed in order of descending

importance:

Specific Nutrition Labeling Requirements and Guidelines

Food and Drug Administration

21 C.F.R. §101.36

Effective March 23, 1999

Summary:

This section covers the regulation of dietary supplements and represents the major FDA response to the DSHEA. It includes information about labeling and notification requirements. In this regulation, the FDA interprets the DSHEA to require that the term “dietary supplement” appear as part of a products statement of identity (i.e., a calcium supplement must be labeled as a calcium dietary supplement). It also provides *extremely* detailed nutritional labeling requirements that are too numerous to summarize but are readily available in the text of the regulation. This regulation is of particular importance because it represents the FDA’s activist response to the DSHEA.

Relevant Federal Register entries that have revised this section:

62 FR 49826 – September 23, 1997 (final regulation)

63 FR 30615, 30620 – June 5, 1998 (final regulation)

Notification Procedures for Certain Statements on Dietary Supplements

Food and Drug Administration

21 C.F.R. §101.93

Summary:

Paragraphs (b) through (e) provide the procedures for the use of a mandatory disclaimer statement on certain dietary supplements. The disclaimer provides that the health claim “has not been evaluated by the Food and Drug Administration” and that the product is “not intended to diagnose, treat, cure, or prevent any disease.”

Relevant Federal Register entries that have revised this section pursuant to the DSHEA:

62 FR 49859, 49867, 49883, 49886 – September 23, 1997 (final regulations)

Requirement for Pre-market Notification

Food and Drug Administration

21 C.F.R. §190.6

Summary:

At least 75 days before a dietary supplement containing a new dietary ingredient enters the market, the manufacturer of the supplement must submit information that is the basis for which the manufacturer has concluded that the supplement is safe. The regulation then outlines the specific requirements of the notification.

Relevant Federal Register entries that have revised this section:

62 FR 49886 – September 23, 1997 (final regulation)

Specific Requirements for Health Claims

Food and Drug Administration
21 C.F.R. §101.71
Summary:

This short section lists prohibited health claims for dietary supplements, such as antioxidant vitamins and cancer.

The following are the most recent proposed rules and notices regarding the regulation of dietary supplements, listed in order of descending importance:

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body

Food and Drug Administration – Proposed Rule
63 FR 23624
April 29, 1998
Summary:

This proposed rule represents the FDA's attempts to define the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The proposed regulations also establish criteria for determining when a statement is a prohibited disease claim. This proposed rule represents the heart of the controversy about FDA regulation of dietary supplements at this time.

Dietary Supplements: Comments on Report of the Commission on Dietary Supplement Labels

Food and Drug Administration – Notice

21 FR 23633

April 29, 1998

Summary:

This Notice announces the FDA's recommendation and guidance about the safety of dietary supplements and the scope of permissible structure/function claims. This notice is very comprehensive and contains a lot of information about relevant statutes and regulations.

Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements

Food and Drug Administration – Proposed Rule
64 FR 3250
January 21, 1999
Summary:

This proposed regulation represents the FDA’s response to the Food and Drug Modernization Act of 1997. Specifically, the FDA addresses the issue of health claims for dietary supplements based on authoritative statements and puts forth the idea that they should be treated in the same manner as health claims for conventional foods.

Food Labeling: Nutrition Labeling of Dietary Supplements on a “Per Day” Basis

Food and Drug Administration – Proposed Rule
64 CFR 1765
January 12, 1999
Summary:

This proposed regulation concerns amending the nutrition labeling regulations for dietary supplements to allow the amount of a dietary ingredient to be presented on a “per day” basis in addition to the already-established “per-serving basis,” if the dietary supplement is to be consumed more than once per day. This is an attempt to provide manufacturers with more flexibility to present additional labeling information to consumers.

Judicial and Executive Materials

In addition to traditional court decisions, the FDA itself makes non-adversarial decisions in the form of private letter rulings. These rulings are very difficult to find in print but can be found on-line. These letters apply to one party only and do not have general precedential effect. However, they do give the legal researcher clues about how a particular agency may proceed. I have found no relevant opinion letters available at this time that address the regulation of dietary supplements. For future legal research, I would suggest contacting the FDA’s own website at <http://www.fda.gov>. It currently contains archived opinion letters from 1980-1992.

The FDA home page is the best source for finding relevant quasi-legislative materials such as guidelines, newsletters and bulletins. Currently, the FDA website contains the following relevant quasi-legislative materials:

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Topical databases on Lexis and Westlaw are also good sources to consult for these materials. Lexis did not have any relevant files at this time, but the following files on Westlaw are very useful:

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Legislative History

Legislative history documents can also be a very useful source for the legal researcher, especially for a relatively recent topic such as the regulation of dietary supplements. The task of finding relevant reports, hearings, and transcripts is much easier for federal statutes, so the legal researcher will find that information is generally readily accessible. Legislative histories can provide important insight into the purpose and history of a particular statute, and courts sometimes consider them in determining the meaning of a statute. Some legislative history documents are more credible than others, as I have explained below.

Finding Compiled Legislative History

If someone else has already compiled a legislative history on a topic, a smart legal researcher will start with that source. The best way to find relevant legislative histories is to do a subject search in an on-line catalog for the LC subject heading “Dietary supplements—law and legislation—United States—legislative history.” I found one book devoted to the legislative history of the DSHEA:

Dietary Supplement Health and Education Act: A Legislative History and Analysis

I. Scott Bass and Anthony L. Young

The Food and Drug Law Institute

1996

319pps.

Summary:

This is a very good source to begin legislative history research. First, the book contains a very detailed summary of the DSHEA and related prior legislation about the regulation of dietary supplements. Specifically, the book contains the full-text of the relevant report from the Senate Committee on Labor and Human Resources. It also contains the full-text of the relevant Congressional Record transcripts of the floor action regarding the House and Senate passage of S. 784, which later became the DSHEA. It also has relevant congressional statements upon the introduction of the House and Senate version of the bill. The major weakness of this legislative history is that it omits entirely all of the relevant hearing information.

A really great source for post-1970 legislative histories is the Congressional Information Service (CIS). CIS does the best job of providing the researcher with already-compiled legislative histories, lists information from previous Congress, and has abstract information. CIS is found in print, on Lexis, and on the Internet.

Congressional Information Service

Bethesda, MD: CIS Publishing
LC Call#: KF49.C62

The print version of CIS is has separate legislative history volumes from 1985 to the present. I easily found the DSHEA by public law number, and CIS provided one relevant report, four relevant hearings, and three relevant excerpts of floor debate in Congress. CIS does not contain the full-text of the legislative history documents; however, it does provide an accession number that allows the researcher to locate the documents on microfilm. Additionally, CIS has abstracts volumes that contain specific information about a particular hearing, etc., such as the names of the parties who testified and the relevant insertions.

CIS is also available through Congressional Universe on Hollis Plus and on Lexis in the LEGIS library; CISLH file. Lexis also has a health-related CIS that is much narrower, however, it did not provide any information on relevant legislative histories.

I found that both CISLH and Congressional Universe provided the same information as the print CIS. One advantage to the on-line versions of CIS, however, is that abstracts are linked by hypertext, which is much easier than having to go to a separate book. Additionally, the on-line format allows for more searching options. For example, Congressional Universe allows the user to search by number (public law, Statutes at Large, or bill number), subject, committee, or keyword.

U.S. Code Congressional and Administrative News (USCCAN) (cited earlier in the Administrative Materials section) can also be used for legislative history research, however, CIS is a better source for post-1970 materials. USCCAN is only available for bills that actually passed, and it does not provide the user with relevant information from previous Congress' (only the Congress that passed the bill). USCCAN for legislative histories is a really a hybrid: it does not contain information about hearings or prints but has some full-text documents such as reports. The one advantage to USCCAN is that it provides references to the U.S.C.A.

Unfortunately, USCCAN had no relevant reports relating to the DSHEA. It only contained three citations to relevant Congressional Record entries.

There are also two other print sources that can be useful for locating these already-compiled legislative histories:

Sources of Compiled Legislative Histories

Nancy R. Johnson
Littleton, CO: Fred B. Rothman & Co.
1996
LC Call#: REF KF 42.2 1979
Comments:

While this source was supplemented in 1996, it does not yet contain any relevant legislative histories. Legislative histories in the source are arranged by public law number, and the public law numbers in the book stop well before P.L. 103-407, the relevant public law number for the DSHEA. For future legal research, this source should be consulted to see if it has been updated to include legislative history information about the DSHEA.

Federal Legislative Histories: An Annotated Bibliography and Index to Officially Published Sources

Bernard D. Reams, Jr.
Westport, CT: Greenwood Press
1994
595 pps.
LC Call#: REF KF 42.2 1994

Comments:

This source contains only official legislative histories and does not provide any relevant information for the legislative history of the DSHEA. It, too, is not current enough to be helpful. This source provides a particularly good abstract, so it too should be consulted for future legal research.

In addition to these sources, both Westlaw and Lexis have full-text, already-compiled legislative histories that are searchable.

The Legislative History Documents for the DSHEA

There are four relevant hearings, one relevant Senate report, and three floor transcripts for the DSHEA. Of the documents, the Senate report is the most credible source, since it reflects the views of the Senate experts in the area. The hearings are less credible sources for legislative intent, since they often reflect two opposite sides of the issue. I have provided the relevant CIS accession numbers in order to locate these documents in CIS microfilm. I have listed these documents in order of descending importance.

Senate Report on the Dietary Supplement Health and Education Act
S. Rpt. 103-410 (to accompany S. 784)

Submitted by Mr. Hatch, from the Committee on Labor and Human Resources
October 8, 1994

49 pps.
CIS NO: 94-S543-15
Summary:

This Senate Report contains a summary of S. 784, an explanation of the background of the need for legislation (the need for greater access to dietary supplements), a summary of the relevant hearing in that committee, and a short explanation of the legislative history and committee action. Additionally, the report gives specific explanations of the committee views regarding the definition of dietary supplements, the safety of dietary supplements, and the burden of proof on the FDA relating to dietary supplement claims. The report also contains a cost statement, a regulatory impact statement, as well as a section by section analysis of the Act. Finally, the report provides additional views by other Senators and describes the relevant changes in existing law.

“Regulation of Dietary Supplements”

Hearing Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

July 29, 1993

630 pps.

CIS NO: 94-H361-15

Summary:

David Kessler (FDA Commissioner) and Samuel Broder (Director, National Cancer Institute) (as well as others) testified and expressed concern about the proposed legislation and the possibility of future unsubstantiated health claims. Various representatives from differing groups testified to the need for decreased regulation of dietary supplements.

“Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 1994. Dietary Supplements”

Hearing Before the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies Appropriations, Committee on Appropriations, House of Representatives

October 18, 1993

374 pps.

CIS NO: 93-H181-90

Summary:

This hearing examined the FDA’s interpretation of the NLEA and the bills (S. 784 and H.R. 1709) to restrict the FDA’s power to regulate dietary supplements. Sen. Hatch and others testified to the need to restrict FDA regulation in this area. Victims of complications regarding the use of dietary supplements and representatives from various interest groups testified to the contrary need for the increased FDA regulation of dietary supplements. David Kessler testified as to the necessity for regulation and related complication regarding regulation.

“Legislative Issues Relating to the Regulation of Dietary Supplements”

Hearing Before the Committee on Labor and Human Resources, U.S. Senate

October 21, 1993

225 pps.

CIS NO: 94-S541-11

Summary:

This hearing was primarily focused on the FDA's regulatory powers under the NLEA, however it did briefly consider S. 784. David Kessler testified to issues relating to unsubstantiated health claims and the safety of various dietary supplements. Representatives from the Nutritional Health Alliance and the Center for Preventative Medicine testified to their concerns about the FDA regulation of dietary supplements.

"Food and Drug Administration's Regulation of Dietary Supplements"

Hearing Before the Subcommittee on Human Resources and Intergovernmental Relations,
Committee on Governmental Relations, House of Representatives

July 20, 1993

518pps.

CIS NO: 95-H401-36

Summary:

This hearing is focused primarily on the dietary supplement issues under the NLEA, however it does provide useful information on differing views regarding FDA efforts to prevent manufacturers of dietary supplements from providing health-related information on dietary supplement labels. Specifically, this hearing contains testimony from food science and nutrition professors endorsing FDA's health supplement labeling requirements to protect consumers.

Senate Consideration and Passage of S. 784
140 Congressional Record, 103rd Congress, 2nd Session

August 13, 1994

pps. S11705-S11715

Summary:

Senator Hatch proposed an amendment to S. 784 to narrow the definition of dietary supplement, to allow structure/function claims, and to provide good manufacturing practice regulations for dietary supplements, among other things. The amendment was passed.

House Consideration and Passage of S. 784 with an Amendment

140 Congressional Record, 103rd Congress, 2nd Session

October 6, 1994

pps. H1173-H1180

Summary:

Rep. Waxman introduced a Statement of Agreement between the House and Senate regarding the DSHEA. The statement of agreement was approved.

Senate Concurrence in the House Amendment to S. 784

140 Congressional Record, 103rd Congress, 2nd Session

October 7, 1994

pps. S14798-S14801

Summary:

The Senate adopted the Statement of Agreement and the compromised bill was passed.

One other document that may be relevant in legislative history research is the Signing Statement by the President. CIS does not provide this relevant information, however the legal researcher can find the relevant signing statement by consulting the Weekly Compilation of Presidential Documents for the date the bill was passed. The Signing Statement for the DSHEA can be found in the:

Weekly Compilation of Presidential Documents

Vol. 30, no. 43

Washington, DC: Government Printing Office

October 25, 1994

p. 2158

LC Call#: J80.A284

The Signing Statement can also be accessed on line in, for example, the LH database on Westlaw.

Finding Bill Tracking Information

A good place to start research in this particular area is the Thomas page of the Library of Congress website (<http://thomas.loc.gov>). Thomas contains a huge amount of information and is literally being changed and updated every day. Thomas offers the following legislative history/bill-tracking features:

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Obviously, Thomas can be used to find the full text of the DSHEA bills. Because of Thomas' ongoing update efforts, the future legal researcher should consult Thomas to see if retrospective coverage is available for the committee reports and hearings.

Thomas is also very useful because it allows the researcher to do a search for recent bills involving the regulation of dietary supplements. (There is a search option by word/phrase). For example, two bills that relate to the regulation of dietary supplements have been proposed (and one passed) since the DSHEA:

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A good print source for finding bill status and tracking information is the CCH Congressional Index.

CCH Congressional Index

Chicago, IL: CCH Publishing
LC Call#: REF KF 49.C6

CCH Congressional Index is inferior to Thomas in that it does not contain the full-text of bills and is not retrospective (new binders issued for each Congress). The researcher using CCH should check all the layers on the subject index (current, latest, etc.). The subject "dietary supplement" contains relevant information, as does the "food" subject, subheading "dietary supplement." To be sure, the researcher should check under both headings when searching for relevant bill information regarding the regulation of dietary supplements.

I found CCH to be a good source for the legislative history information regarding S. 784 (see the “Status of Senate Bills” tab, arranged by bill number, in the 103rd Congress binder). It explains that S. 784 went through the following path before final passage:

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In addition to these sources, Lexis and Westlaw contain the following very useful databases:

Lexis:

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Westlaw:

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Generally, searching for the phrase “dietary supplement” in these files is much too broad unless the file is narrowed to a particular Congress or year. If the file is narrow, searching for “dietary supplement” is the best option. It is more difficult to formulate a term search for the combined files that does not under-retrieve (for example, “dshea” under-retrieves), so the legal researcher should try to narrow the database as much as possible either by Congress or by year.

Finding Relevant Cases

There are countless ways to find relevant cases ranging from on-line databases such as Westlaw and Lexis to finding citations in relevant secondary material. I have listed these sources and explained their effectiveness below.

Full-Text Searching in Westlaw and Lexis

The fastest and most efficient method for finding relevant cases is the full-text search method in Westlaw or Lexis. Before searching in the larger, combined databases that include all federal case law, the legal researcher interested in decreasing costs should first consult the following topical databases on Lexis and Westlaw:

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I found that searching in the topical databases retrieves all of the most relevant cases. This option saves costs while at the same time sacrifices little in accuracy for this particular topic.

The following search query proved to be the most effective:

“dietary supplement” /s regulat! & DA(>1993) – Westlaw
dietary supplement w/s regulat! and (appropriate date restriction) – Lexis

NOTE: When searching for case law under this topic, it is absolutely imperative to narrow the search query as much as possible. Searching under “dietary supplement” is effective for some smaller resources, but massively over-retrieves for case research.

Key Number Searches

Since the regulation of dietary supplements can involve a number of different areas of law (first amendment, regulatory and administrative law), the West's key number system is a good way to narrow down the search to only the cases relevant to the DSHEA and regulation of dietary supplements. Key numbers can be found using the Descriptive Word Index, case headnotes, and secondary sources such as ALR. When searching in West materials, the following key numbers are the most relevant, listed from most relevant to least relevant:

138k2 – Drugs and Narcotics – Federal Regulations

138k3 – Drugs and Narcotics – Drugs or Devices within Regulations

178k1.7 – Food – Power to Make Regulations – Administrative Power in General

138k7 – Drugs and Narcotics – Labeling Requirements

90k09.2 – Constitutional Law – Freedom of Speech and the Press – Commercial Speech in General

Internet Sources for Finding Cases

There are a number of Internet sites that allow the user to search for cases using a keyword method. The following cites retrieved most of the relevant case law using the broad search for “dietary supplement.”

In addition to these free sights, there are also commercially-licensed databases available through subscription such as Lois and Versus Law. Lois is accessible through Nellco (www.nellco.org). Although these databases have more limited search capabilities, they are much cheaper than Lexis or Westlaw. I found that searching on Lois in the all federal category for “dietary supplement” retrieved nearly all the relevant cases.

Citator Services

The legal researcher should take advantage of the various citator services available such as Shepard's on Lexis or Keycite on Westlaw. Not only do citator services provide information on the authority of the case, they also lead the legal researcher to other relevant cases. Relevant cases should be checked using citator services in the future to determine if any relevant cases or secondary materials have cited the most relevant cases in this topic area.

To assist the future legal researcher using Keycite or other citator services, I have provided the relevant West headnote numbers after the summary of each relevant case below.

Digest Searching for Cases in Print

The traditional way to find relevant case law is to use the digest method. Since the regulation of dietary supplements is inherently federal in nature, the researcher should first consult the Federal Practice Digest 4th in order to find the most recent cases. To begin the search, consult the Descriptive Word Index. While there is no digest subject heading or sub-heading for “dietary supplements,” I found the most relevant headings to be “Food” and “Drugs and Narcotics.” The Descriptive Word Index leads the researcher to the relevant digest headings and subheadings. Since this topic involves very recent cases, the researcher should be very careful to check all relevant pocket parts.

Federal Practice Digest 4th (1989-)
St. Paul, MN: West Publishing
LC Call#: KF 127.W48x

The most difficult part about using the digest method was the elusiveness of relevant sub-headings. I literally had to read nearly all the entries under the broad headings listed above in order to find relevant cases. The most relevant sub-heading under Food was “Administrative Power in General,” and the most relevant sub-heading under Drugs and Narcotics was “Federal Regulation” For other relevant subheadings, see the list of relevant key numbers below. Finding relevant cases in this topic area is definitely more frustrating when using the digest method.

Finding Cases Using Law Reviews and Periodicals

The law reviews and periodicals cited in the Legal Periodicals section of this guide can be very useful in finding the most important cases in the topic area. Generally, the footnotes of law review articles provide a wealth of information that will lead the legal researcher to relevant cases. Furthermore, some articles even contain lists of relevant cases. The legal researcher should be sure to consult the latest law review articles to gain an understanding of the leading cases in the topic area.

American Law Reports (ALR)

American Law Reports
Rochester, NY: Lawyer’s Cooperative Publishing Company
LC Call#: KF 132 A47

ALR is a hybrid – it is a selective court reporter and annotations service. ALR is also extensively updated, so the legal researcher can find the most current information on a topic. Consequently, ALR in print can

be a confusing source for the legal researcher. The best way to begin a search is to use the index. For ALR Federal (the most relevant version of ALR for researching the regulation of dietary supplements), check the ALR Federal Quick Index under the subject headings “Drugs and Narcotics” and “Food, Drug, and Cosmetic Act.” From the index, the researcher should check the citations in the main volume and update the main volume using the Bluebook of Supplemental Decisions, Later Case Service, or pocket parts, depending on which version of ALR is being updated. For ALR Federal, the researcher should be sure to check the pocket parts.

On-line versions of ALR are much more user-friendly. ALR is available on Westlaw as ALR and on Lexis in the ALR library; ALR file. I started searching these databases with narrow search queries, but I found that the most effective queries were the following:

(dietary /3 supplement) & DA(>1993) (Westlaw)
(dietary w/3 supplement) & appropriate date restriction (Lexis)

While ALR can be a useful source for finding cases about a very focused area of law from many jurisdictions, ALR was only marginally helpful in locating cases relevant to the regulation of dietary supplements. I found only one article that is potentially useful for the legal researcher:

“What is ‘Drug’ Within Meaning of § 201(g)(1) of the Federal Food, Drug and Cosmetic Act”

127 ALR Fed 141 (1995)

Jay M. Zitter
Summary:

As the title indicates, this annotation gives a summary of what is and what is not a drug under the Federal Food, Drug and Cosmetic Act. Further, it points to various ambiguities in the definition of “drug” within the Act. The most relevant part of the article is § 42 on Food Supplements. This section lists various cases where dietary supplements have been held to be a drug and where dietary supplements have been held not to be drug. The case citations are pre-1994; therefore, they do not provide any directly relevant information. However, this section is worth reading in order to get an idea of the fine line between dietary supplements and drugs.

Finding Cases Using Words and Phrases

Words and Phrases
St. Paul, MN: West Publishing
LC Call#: KF 156.W6712

Words and Phrases is provides citations to cases that define a term or phrase. Under the topic “dietary

supplement,” I found one case that mentioned that a particular article was not a dietary supplement. (See US v. 10 Cartons, More or Less, of an Article Ener-B Vitamin B-12 in the Most Relevant Cases section.) Therefore, I would not highly recommend this source for this topic.

Words and Phrases is also available on Westlaw (but not Lexis) as a “WP” field search. The following field search retrieved the relevant case:

WP (“dietary supplement”) & DA (>1993)

The Most Relevant Cases

There is not yet an abundance of cases addressing the DSHEA’s impact on the regulation of dietary supplements. However, there are many cases that address the first amendment as it relates to the labeling requirements of dietary supplements under the NLEA. Since that topic is only indirectly relevant (the DSHEA carves out an exception to the NLEA), I have not included the leading NLEA cases, unless they provide relevant insight into the DSHEA.

The following are the leading cases (listed from most relevant to least relevant) that address the DSHEA’s impact on the regulation of dietary supplements:

Pearson v. Shalala

164 F.3d 650 (-660), Suggestion for Rehearing en Banc Denied by Pearson v. Shalala, — F.3d —, 1999 WL 178712 (D.C.Cir. Apr 02, 1999)

United States Court of Appeals, D.C. Circuit

January 15, 1999

Summary of Holding:

The Court ruled that the FDA must define “significant scientific agreement,” the standard currently used by the FDA in authorizing health claims on dietary supplements. Additionally, this case held that certain health claims were not inherently misleading, and the FDA must consider whether the required disclaimer on the dietary supplement label negates the misleading nature of the health claims under the commercial speech doctrine.

Relevant Headnotes: [2], [3], and [6]
Pharmanex, Inc. v. Shalala

35 F.Supp.2d 1341 (-1349)

United States District Court, D. Utah

February 16, 1999
Summary of Holding:

This case is a review of an FDA administrative decision that held that capsules containing milled red yeast rice (Cholestin) are drugs rather than dietary supplements. The exclusionary clause in the DSHEA is at issue in the case. The clause states that an article is a dietary supplement if it was approved as a new drug but marketed as a dietary supplement prior to the approval (and not a dietary supplement if it was not). The FDA found that Cholestin was a drug, not a dietary supplement, based on its lovastatin content. Lovastatin was found to be a drug before 1987, before Cholestin was manufactured as a dietary supplement. The court, interpreting the DSHEA, found that “new drug” referred to finished drug products, not to components of drug products. Therefore, the FDA’s ruling that Cholestin is a drug was overturned.

Relevant Headnote: [4]

US v. 10 Cartons, More or Less, of an Article Ener-B Vitamin B-12

888 F.Supp 381 (-418)
United States District Court, E.D.N.Y.
March 24, 1995
Summary:

This lower court case describes in detail the DSHEA and holds that article is not a dietary supplement under the DSHEA.

Relevant Headnotes: [2], [3], [4], [5], [9], [10], [12], [13], [16], [17], and [21]

US v. 10 Cartons, More or Less, of an Article Ener-B Vitamin B-12

72 F.3d 285 (-287)
United States Court of Appeals, Second Circuit (New York)
December 19, 1995
Summary of Holding:

The Court found that the FDA did have authority to regulate the vitamin supplement as a drug. In so holding, the court found that a dietary supplement’s status as a food or drug should be determined by the application of the subsection of the Federal Food, Drug and Cosmetic Act (amended by the DSHEA) that defines an article intending to affect the structure or function of the body as a drug, and not by the subsection that defines dietary supplements as food. This case also explains in detail the DSHEA.

Relevant Headnotes: [1] and [2]

Nutritional Health Alliance v. Shalala
144 F.3d 220 (-228)
United States Court of Appeals, Second Circuit (New York)
Petition for Writ of Certiorari Denied, 119 S.Ct. 589 (Dec. 7, 1998)
May 15, 1998

Summary of Holding:

This case held that the NLEA's requirement for prior approval of all health claims appearing on dietary supplement labels is not an un-Constitutional prior restraint of commercial speech. Specifically, it explains the DSHEA's exception to the NLEA that certain claims regarding dietary supplements can be made without petitioning the FDA.

Relevant Headnotes: [5], [6], and [8]

Nutritional Health Alliance v. Shalala

953 F.Supp 526 (-532)

United States District Court, S.D.N.Y.

January 31, 1997

Summary:

This lower court decision, while discussing primarily prior restraint issues and the NLEA, also discusses the policy of the DSHEA.

Relevant Headnotes: [1] and [2]

Legal Periodicals

Legal periodicals are an excellent source for finding information about the regulation of dietary supplements. Legal periodicals can include law reviews, bar journals and newsletters, commercially-published specialized journals, legal newsletters, and legal newspapers. While searching legal periodicals yields a great deal of information about dietary supplements, I have only included the best articles and sources below.

Finding Periodical Titles

Searching for periodical titles is one way to research the broad array of periodicals that may have relevant articles. Once a periodical title is found, the researcher can search within the periodical using a cumulative index (either print or on-line).

Periodical titles can be found using both print and on-line resources. The Encyclopedia of Legal Information Sources is a useful print source to use if the researcher is unfamiliar with the topic. The major disadvantage to this source is that it is dated. Another good source that is particularly useful for finding annual and survey issues of legal periodicals is Annuals and Surveys Appearing in Legal Periodicals. This source did not yield any relevant annual or survey editions regarding food and drug law specifically. There are survey editions of periodicals on the topic of health care law generally, however, they contained no relevant articles on the regulation of dietary supplements. The legal researcher should consult these sources for future research in order to determine whether the health care law annual editions contain any relevant articles relating to the regulation of dietary supplements.

Citations to Print Sources:

Encyclopedia of Legal Information Sources, 2nd Ed.
Detroit, MI: Gale Research, Inc. (1993)
pps. 384-387
LC Call# Ref KF1 E53

Annals and Surveys Appearing in Legal Periodicals

Catherine L. Kerr

Littleton, CO: Fred B. Rothman & Co. (1996)

145 pps. plus supplement (Health law information on p. 112)

LC Call# Ref KF 8.K4

On-Line Research for Periodical Titles

One way to find periodical titles on-line is to use a local library's on-line catalog system (HU for Hollis). This search will only yield those periodicals contained within the library itself. The best way to formulate a search in on-line catalogs is to use the Library of Congress subject heading or a keyword within the subject heading with the addition "periodicals" in the search query. On Hollis Plus, the researcher can do a format search limited to serials ("//FO=SER" at the end of the search query) to yield looseleaf services, annual directories, etc, in addition to periodicals.

For a broader on-line search for periodical titles, the researcher can use Ulrich's International Periodicals Directory. Ulrich's is available on Westlaw as ULRICHS and on Hollis Plus.

There are no periodical titles specifically devoted to the regulation of dietary supplements. There are, however, broader titles dealing with food and drug law and the FDA in general. The following titles could be useful for the researcher:

Food and Drug Law Journal (1992 -)
Formerly, Food Drug Cosmetic Law Journal (- 1991)

Food and Drug Law Institute

Quarterly
Availability:

Harvard Law School Library: 1992-1997 and current receipts
Westlaw: FOODDLJ, selected coverage from 1992 -

Lexis: LAWREV library, FADLJ file, full coverage from 1996 vol. 51 no.

4 – current

Internet: Food and Drug Law Institute Website – www.fdli.org, coverage of vols. 52-5

Journal of Pharmacy and Law (1992 -)

Ohio Northern University Pharmacy-Law Institute

Availability:
Harvard Law School Library: vol. 1-5, 1992-1995

Westlaw: JPHARML, coverage begins in 1992, full coverage
from 1993-1997

Finding Periodical Articles from Periodical Indices

Searching by periodical index is the most effective way to find articles relevant to the regulation of dietary supplements. There are several indices available to the researcher, including the Legal Resource Index, the Current Law Index (a subset of the Legal Resource Index), and the Index to Legal Periodicals and Books (ILPB). Each of these indices has advantages and disadvantages with respect to researching articles pertaining to the regulation of dietary supplements.

The Different Periodical Indices

For the researcher interested in the regulation of dietary supplements, the Legal Resource and Current Law Indices are much better sources than the ILPB. The Legal Resource Index is available on Hollis (LR), Westlaw (LRI), Lexis (LEXREF library; LGLIND file) and on CD-Rom as Legaltrac. It only dates back to 1980, which is not a disadvantage since the articles relevant to dietary supplement regulation would not appear before then. Both the Legal Resource and Current Law Indices generally use Library of Congress subject headings. In contrast, the ILPB has subject headings that are “made up” and not congruent with the Library of Congress subject headings. The Legal Research and Current Law Indices both index legal newspapers and legal articles appearing in non-legal journals, whereas the ILPB does not. The Legal Resource Index

has no page limits and can index very short articles, and the ILPB does not have that advantage. Finally, the Current Law Index has a more complete Table of Cases and Table of Statutes.

Index to Legal Periodicals and Books

New York, NY: H.W. Wilson Co. (1926-)

LC Call#: REF K 33.I545

Current Law Index

Los Altos, CA: Information Access Corp. (1980-)

LC Call#: REF K 33.C87

Legal Resource Index

Foster City, CA: Information Access Corp. (1980-)

LC Call#: REF K 33.L44b

Current Index to Legal Periodicals

Seattle, WA: Washington Law Review (1984-)

LC Call#: REF K 33.C86

In addition to these indices, there are other on-line indices available to the legal researcher. One example that could be useful for researching the regulation of dietary supplements is the Public Affairs Information Service (PAIS) available on Hollis Plus. This database indexes books, government documents, and periodical articles about public policy. While the database currently contains no relevant articles, it may be a good source to consult for future research.

Searching Periodical Indices

I have found that the most efficient means of searching these indices is the LRI option on Westlaw. Westlaw provides hypertext links to the full-texts of the articles in LRI available on Westlaw, which saves an enormous amount of time for the legal researcher. The following search query proved to be the best for searching any on-line Legal Resource Index:

DE ("dietary supplements" /s regulation) (picks up the LR subject heading dietary supplements
–laws, regulations, etc, as well as other relevant articles)

Searches using the Legal Resource and Current Law Indices can be updated by using the Current Index to Legal Periodicals (available on WL as CILP and on the Nellco site at <http://www.nellco.org>. The CILP is a smaller index

and only contains the most recent articles before they are put into the LRI. Thus, when searching in this index, a researcher can use a broader search query such as “dietary supplement.”

Narrow, Topical Indexes

In addition to the broad indices, a legal researcher should be aware of more narrow indices. There is no narrow index relating to dietary supplements at this time. The health law indices that are available are no more useful than the broader indices, however they are much narrower. For the legal researcher who is interested in avoiding the costs of the larger, combined files, the following indices on Westlaw are just a few of the many indices that should be searched first for relevant material.

FOODDLJ – Food and Drug Law Journal

JPHARML – Journal of Pharmacy and Law

HTH-TP – Health and Medicine Law Reviews, Texts, and Bar Journals Combined.

On Lexis, there are a variety of topical resources in the Health Care (HEALTH) library. Additionally, the Hot Topics (HOTTOP) library often contains articles about the FDA in the health law section.

On-Line Periodicals:

There are various websites for the legal researcher to consult for relevant periodical articles. The USC Law Library Law Reviews web site (<http://www.usc.edu/dept/law-lib/legal/journals.html>) has links to specific law reviews. The USC site also has links to ABA journals and newsletters, commercial law journals, and other periodicals. Findlaw (www.findlaw.com) and Washlaw (www.washlaw.edu/lawjournal/lawjournal.html) have similar links to selected periodicals. The legal researcher should be aware that the word searches on some of these sites yield only sparse and random results.

Best Periodical Articles:

The following are the most useful articles, either for their content or footnoting, relating to the regulation of dietary supplements. I have listed them in descending order of helpfulness and importance:

“Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice”

49 Fla. L. Rev. 663

Margaret Gilhooley

Dec. 1997

pps. 663-724

Summary:

This article has a very good in-depth discussion of all aspects of the DSHEA, a comprehensive introduction and conclusion, and very extensive footnotes. It is sympathetic to the FDA’s point of view and expresses concerns that unsubstantiated health claims could be placed on dietary supplements. This article is an essential read for those researchers interested specifically in the consumer protection point of view. It also discusses specific ambiguities and limitations of the DSHEA, examines ways to distinguish disease from structure/function claims, and details what manufacturers should be doing to substantiate health claims. The author of the article worked in the Chief Counsel’s office of the FDA.

“FDA Regulation of Ingredients in Dietary Supplements after Passage of the Dietary Supplement Health and Education Act of 1994: An Update”

51 Food & Drug L.J. 313

Stephen H. McNamara

1996

pps. 313-318

Summary:

This article discusses the specific requirements for the regulation of dietary supplements after the Dietary Supplement Health and Education Act (DSHEA). Specifically, it details the expanded definition of dietary supplement, the exemption of dietary ingredients in the supplements as food additives (thereby escaping regulation if not generally regarded as safe), the new safety standards for dietary supplements, and early FDA implementation and enforcement actions. The article has a very straightforward, explanatory tone. The legal researcher should be aware, however, that many references in this article are out of date as regulations have changed dramatically since 1996.

“Ambiguities of the Dietary Supplement Health and Education Act of 1994”

51 Food & Drug L.J. 383

Robert G. Pinco and Paul D. Rubin

1996

pps. 383-398

Summary:

This article asserts the position that the FDA has not exercised the authority it does have under the DSHEA. It particularly focuses on the controversy surrounding ephedra and has an extensive description of all aspects of the DSHEA. It discusses briefly acceptable advertising claims and state enforcement and pre-emption issues.

“Dietary Supplements: Background for Dialogue Between the Industry and Medical Profession”

53 Food & Drug L. J. 413

Arnold I. Friede

1998

pps. 414-420

Summary:

This article, written by the former Chief Counsel for the FDA, focuses on the current labeling requirements under the DSHEA and discusses flaws in proposed FDA regulations, specifically the one relating to structure/function claims in the safe harbor provision of the Food, Drug, & Cosmetic Act. It is very critical of the FDA’s decision to define disease broadly and to eliminate structure/function claims from the safe harbor provision.

“Health Law”

75 Denv. U. L. Rev. 953

Christyne J. Vachon

1998

pps. 965-969

Summary:

This article explains the DSHEA in the context of the Nutrition Labeling and Education Act (NLEA) that required standardized labeling and prohibited manufacturers from making false claims. It has a separate section for dietary supplements and discusses in depth relevant cases. The article has extensive footnotes.

“Regulating Dietary Supplement Safety under the Dietary Supplement Health and Education Act: Brave New World or Pyrrhic Victory?”

51 Food & Drug L. J. 319

Bruce A. Silverglade

1996

pps. 319-321

Summary:

This is a short article that criticizes the public policy side of the DSHEA. It notes that the DSHEA will decrease consumer confidence in the safety of supplements and urges food companies not to use the DSHEA as a model for future reform.

“Confusion in Dietary Supplement Regulation: The Sports Products Irony”

77 B.U. L. Rev. 181

Jennifer J. Spokes

Feb. 1991

pps. 181-207

Summary:

This article uses the sports products example to illustrate the need for the increased regulation of dietary supplements. It advocates an intermediate level of scrutiny for certain supplements that may pose particular health and safety concerns, such as sports products. Although this is a student note, it does contain good footnotes and is very often cited in other secondary material.

“The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994”

21 Seton Hall Legis. J. 200

Peter A. Vignuolo

1997

pps. 200-31

Summary:

This article has a good table of contents and extensive footnotes. Its major disadvantage is that it is a student note. It discusses the legislative history and proposed amendments to the DSHEA, the Committee on Dietary Supplement Labels that administers the DSHEA, and the state reactions to the DSHEA. Its primary focus is the ephedra controversy.

Legal Newspapers

Legal newspapers can be a good source for information on dietary supplement regulation. They tend to contain short articles that do not go into extensive detail, but do lead to relevant primary sources such as cases and statutes, as well as the names of important organizations actively involved with the regulation of dietary supplements. Also, because the regulation of dietary supplements has been such a controversial topic lately, legal newspapers are likely to pick up on the controversy and give the legal researcher a lot of basic, but useful, information.

Finding Articles in Legal Newspapers

Many legal newspapers are available on-line. Both Westlaw and Lexis contain legal newspaper databases. The following combined databases on Westlaw and Lexis are useful:

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In addition to the combined newspaper files, both Lexis and Westlaw have individual newspaper files as well. Because these files tend to be smaller and the articles shorter, the researcher can run a search for “dietary supplements” (the best search) or “nutritional supplements.” This is common terminology and does not result in massive over-retrieval. If a narrower search is desired, the researcher can try “dietary supplements” /s regulation.

When a newspaper is found, it may very well save costs to consult the relevant website for that newspaper in order to determine if archived issues are available on-line. Legal newspapers are also indexed in the Legal Resource Index.

The Best Legal Newspaper Articles:

The following articles are the most timely and relevant articles relating to the regulation of dietary supplements from legal newspapers:

“Are Dietary Supplements a Food, Drug, or Drag?”

Eric F. Greenberg

The National Law Journal, vol. 21, no. 29

p. A24

March 15, 1999

Summary:

This newspaper article discusses acceptable and unacceptable disease claims under the DSHEA and points to the fact that the regulatory scheme is not fully developed.

“Vitamin Ruling Bitter Pill for FDA”

Carrie Johnson

Legal Times, vol. 21, no. 39

p. 1

February 22, 1999

Summary:

This article discusses the very recent court case (Pearson v. Shalala) that mandated the FDA to fully explain its standard for regulating dietary supplements. This is the first case in which an appellate court has addressed the issue.

“Dietary Supplements Caught in Murky Regulatory Scheme”

Eric F. Greenberg

Chicago Daily Law Bulletin, vol. 144, no. 250

p. 5

December 23, 1998

Summary:

This newspaper article examines the history leading up to the DSHEA and criticizes the FDA for making the definition of disease too broad. It lists specific examples of claims that are considered by the FDA to be disease claims.

Newsletters

Legal newsletters can be great sources, but are often hard to find. They are not indexed in the traditional periodical indices, so the researcher must look into other sources such as interest group websites to find them. Legal newsletters can potentially provide very topical, current information on a particular subject, but the researcher must pay close attention to the source and currency of the information. Because the regulation of dietary supplements is a hot topic, legal newsletters are very helpful.

Finding Relevant Newsletters

One very good print source to consult is Legal Newsletters in Print 1998.

Legal Newsletters in Print 1998

Teaneck, NJ: Infosources Publishing (1999)

LC Call# Ref Desk KF 1.L44

p. 105 (and subject index in back)

This is an annual source, so it will be relatively current. To find newsletters on the topic of regulation of dietary supplements, consult the index heading Food, Drugs, Cosmetics.

There are also many newsletters available at various websites on the Internet, often at law-firm sites and interest group sites.

Examples of Relevant Newsletters

While there are some newsletters that address dietary supplements, they generally focus only on the nutritional aspects of the supplements and do not address any legal issues. There are general newsletters about FDA policy that do address dietary supplement regulatory issues, especially since it is a particularly controversial topic within the broader arena of FDA regulation. The following are just a few examples:

Food and Drug Packaging

St. Charles, IL: Independent Publishing Company

Summary:

This newsletter is published monthly and is more narrowly focused on packaging issues. Since many dietary supplement regulatory issues concern labeling guidelines, this newsletter is particularly useful. The newsletter can be accessed on-line for free at <http://www.fdp.com> by filling out a short registration form. It is also available on Westlaw as FDDRPKG, with coverage beginning January 1, 1994.

FDA News: Drugs, Devices, Cosmetics, and Biologics

Lancaster, PA: Technomic Publishing Company, Inc.

Summary:

This newsletter is published monthly and covers the entire spectrum of FDA issues. It can be accessed free on-line through its publisher's website, <http://www.techpub.com>. In order to access the newsletter, the researcher must fill out a short registration form.

Food and Drug Letter

Arlington, VA: Washington Business Information, Inc.

Summary:

This newsletter focuses primarily on analysis and evaluation of the FDA's regulations, internal procedure, decisions, and policy changes. It also counters industry developments relative to FDA policy.

Food Labeling News

This Dow Jones newsletter is available on-line on Westlaw as FOODLBN, with coverage beginning in October 1992. It is published weekly and contains labeling, packaging and advertising news from the FDA.

In order to receive the latest information from the above newsletters available on Westlaw, the researcher can set up a Westclip search that will automatically search for the latest information retrieved from a specified search query. To set up a Westclip, simply click on the paperclip icon at the top of the query results screen. Add the current query and fill out the template boxes to specify the frequency the query will be run, when notification will occur, etc. I suggest the following search query for Westclip searches in these databases:

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Lexis has a similar function called Eclipse. To set up an Eclipse search, just click on the Save as Eclipse option that appears on the query results screen and fill out the template form to reflect how often the search should be run. All new information will then be sent to you through this service using the query that you specified.

Looseleaf Services

Looseleaf services are a great source because they allow the researcher to gather a lot of different material about the regulation of dietary supplements. Often, looseleaf services contain the full text of relevant statutes, cases, regulations, and contain editorial material. Their main advantage is that they are usually extremely current. While in the past looseleaf services were only available in print, increasingly they are becoming available on line as well.

Finding Print Looseleaf Services

One of the best places to start the search for relevant looseleaf services is:

Legal Looseleafs in Print

Ed. Arlene L. Eis

Teaneck, NJ: Infosources Publishing

1999

LC Call#: REF DESK KF1.L43X

This source contains a great subject index that refers the researcher to all the relevant looseleafs in a particular topic area. The most relevant subject heading was “Food Drugs Cosmetics” found on p. 632 of the subject index. I found two highly relevant looseleafs in print:

Food Drug Cosmetic Law Reports

Six volumes, supplemented 50X/year

Chicago, IL: CCH Publishing

LC Call#: KF 3866.5

Summary of content:

This reporter contains the full text of relevant statutes, cases, regulations, etc. as well as editorial materials. The researcher should be sure to consult the “How to Use This Reporter” tab before beginning. The two most relevant volumes are the Federal volume and the New Matters volume. The topical index in the Federal volume under the topic “dietary supplement” will lead the researcher to relevant statutes, including the DSHEA, and relevant dietary supplement regulations. The New Matters volume contains a layered index, so the researcher should be sure to consult all layers. At this time, there are two layers: the current topical index (current through 4/19/99) and the topical index (current through 3/1/99). This will lead the researcher to the most recent regulations. The references are to paragraph numbers, and the two most important paragraphs in the New Matters volume at this time are Paragraph 42, 197 and Paragraph 45,898 (relevant new regulations, all are listed in the Administrative Materials section of this guide).

Guide to U.S. Food Labeling Law

Ed. Christine Simmon

2 volumes, supplemented monthly
Thompson Publishing Co.

1991

LC Call#: KF 3875.A6

Summary:

This looseleaf contains comprehensive information regarding compliance with the Nutrition Labeling and Education Act. It is organized into topical tab divisions. Tab 900 is devoted to dietary supplements and covers relevant regulations that affect dietary supplement labeling pursuant to the NLEA. Additionally, it explores effectively the distinction between foods and drug and the place of dietary supplements along that continuum.

When using print resources, the researcher should be aware that spin-off volumes which may are may not be cataloged may be available. Be sure to look on the shelf near the looseleaf for any relevant spin-off volumes, and be alert to on-line catalog search results that could be a spin-off volume. The above looseleafs did contain spin-off volumes, however, none were related to the regulation of dietary supplements.

On-Line Sources

The print looseleafs can be very complicated to use, so an easier alternative may be to consult the on-line versions. However, be sure to check the scope notes to see if the looseleaf has been fully integrated on-line. Generally, I found the on-line looseleafs easier to use but less informative than their print counterparts.

The following looseleafs on Lexis should be consulted to find relevant information about dietary supplements. The best search query is “dietary supplement” limited to title, headline, or other counterpart.

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“FDA Told to Permit Proper Disclaimers for Health Claims on Dietary Supplements”

Vol. 8, no.5, p. 180

February 4, 1999

Summary:

This article explains the implications of the Pearson v. Shalala case that allows dietary supplement manufacturers to include health claims on labels as long as there is a disclaimer.

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“U.S. Supreme Court Denies Review of Rule Governing Dietary Supplement Claims”

Vol. 3, no. 24

December 18, 1998

Summary:

This article briefly explains the Supreme Court’s decision to deny certiorari in Nutritional Alliance v. Shalala.

The following looseleaves on Westlaw should also be consulted:

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The information in the looseleafs on Lexis and Westlaw can also be sent to the researcher periodically through the Westclip or Eclipse service on Westlaw and Lexis, respectively.

Finally, the internet may contain relevant looseleafs that are offered on-line for a free-trial period. The following major publisher websites should be consulted for relevant looseleafs available for a free trial:

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Non-Legal Sources

Because the regulation of dietary supplements involves more than just legal information, non-legal sources can be a great way for the legal researcher to gain broad knowledge about the topic. Additionally, non-legal sources can be an effective way to get straightforward and concise legal information. Because there are so many relevant sources of non-legal information, I have only chosen what I consider to be the best representation of each source. Therefore, for future research, the sources I have listed should be consulted first. I have also included tools for the legal researcher to expand the search outwardly if necessary.

Non-Legal Newspapers

Non-legal newspapers provide concise information in an easy-to-digest form and can be very up to date. The easiest way to find these newspapers is on-line, either on Lexis or Westlaw. Many newspapers contain relevant articles about the regulation of dietary supplements, however The Washington Post contains the most informative articles. Specifically, the “Federal Page” in the Legal Section contains extensive coverage of regulatory agencies, making The Washington Post the best place to begin research in this area. Westlaw and Lexis contain databases of all major newspapers that could also be consulted. In addition to searching individual newspapers, both Lexis and Westlaw contain larger, combined newspapers files. The following combined files should be consulted only after narrower searches in order save costs:

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The Washington Post can be found on Westlaw as WP (coverage from January 1984) and on Lexis in the NEWS library; WPOST file (coverage from January 1977). Using the search query TI (dietary /3 supplement) and AD (AFT 1993), I found several relevant articles. Two of the most relevant were:

“Dietary Supplements Gaining Public Approval, If Not Governments”
Susan Okie
The Washington Post

November 25, 1997

p. A01
Summary:

This article generally discusses the DSHEA and its impact on government regulation – i.e. a dramatic decrease in regulation. It also points out that consumers should be concerned about the potential safety hazards of dietary supplements. This article’s main virtue is that it provides a simple and concise explanation of the DSHEA.

“FDA Sets Labeling Rules for Dietary Supplements; Nutritional Data Support for Health Claims Required”
John Schwartz

The Washington Post

June 15, 1993

p. A03

Summary:

This article, read in conjunction with the above article, provides a great look at the status of regulation immediately prior to the DSHEA. Additionally, it provides insight into the consumer reaction that sparked the passage of the DSHEA.

The Internet

The internet can be a great source for finding relevant non-legal information about the regulation of dietary supplements if the researcher keeps its following inherent limitations in mind:

(1)

(2)

(3)

The researcher should be on the look out for relevant sites in bar journals, computer journals, on television, and any other place references to sites may be found. Additionally, a search engine will provide relevant websites. When using any search engine, be sure to use the advanced search option and take advantage of the “Help” or “Frequently Asked Questions” section in order to learn how to craft specific searches. There is no one search engine that will retrieve every relevant site on the internet, so the researcher should consult more than one. I suggest the following searches using search engines:

(1)

(2)

My results were very different from search engine to search engine, so it is extremely important to double check one search engine’s results with another search engine. In addition to these searches, you can also consult the Health directory, sub-directories “Nutrition” and “Web Directories” on Yahoo (<http://www.yahoo.com>) in order to find more relevant websites.

There are literally hundreds of relevant websites for this topic. I have listed and summarized the five most relevant below:

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Topical Files

Both Lexis and Westlaw contain relevant topical sources that can provide a lot of non-legal information about dietary supplements. Dialog on Westlaw contains some relevant databases, however the researcher should be aware that Dialog operates differently on Westlaw than a traditional Westlaw database. Dialog databases contain a range of pricing and transactional charges could apply. Before using any Dialog database, be sure to check the scope note in order to find the exact pricing scheme for that database. Additionally, many Dialog databases are not full text, and many contain phrase-indexed fields that require exact terminology in the search. Scope will provide this information as well. I suggest the following search query for future research in these databases on Westlaw and Lexis:

“((dietary food) /s supplement) /p regulat!” with the appropriate date restriction to retrieve documents after 1993

The following three Dialog databases on Westlaw should be checked for potentially relevant information in the future, though they do not have any relevant information at this time:

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This database is ideal for checking the status of regulation of a particular dietary supplement in the U.S., as well as other countries.

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This database provides citation and abstract information for various articles (international and U.S.) regarding the scientific side of the regulation of dietary supplements

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This database is a good source to find relevant citations to bio-medical literature about the regulation of dietary supplements. To find the most relevant articles, I suggest the following narrower search for this database: AB(“dietary supplement” & (FDA /p regulat!) (there is no date restriction available for this field).

Lexis-Nexis also contains relevant non-legal topical databases. The following databases should be consulted in order to find relevant articles in the future, although they do not have any relevant articles at this time:

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This database contains information about government programs and services related to food and nutrition.

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This database is ideal to check in order to get the very latest information about dietary supplements.

In order to find additional relevant databases in Westlaw and Lexis, the researcher can consult the IDEN database on Westlaw or Search the Source Directory on Lexis for relevant terms such as “food” or “food and drugs.”

People and Organizations

People and organization sources can be a very informative source. People know things that are not necessarily available in written form and can communicate that information in an easy to understand form. They can answer direct questions and can refer the researcher to other people sources. However, the legal researcher should try to obtain as much written information as possible to comply with the constraints of legal research and its emphasis on written material. Additionally, researchers should be aware of the potential bias that can be present in information obtained from people and organizations. Finally, researchers should try to contact relevant people and organizations early in the research process, since it may take a while to reach the person or obtain the relevant written information from the organization.

Finding Relevant People and Organizations

There are several general sources that can be helpful in finding people and organizations involved with the regulation of dietary supplements. Directories can often be very useful for this task. A good place to begin the search for relevant directories is [Directories in Print](#):

Directories in Print

Ed. Dawn Conzett DesJardins
Detroit, MI: Gale Publishing Co.
LC Call#: REF AY 2001.D572x
Summary:

This is literally the directory of directories. To find relevant directories in this book, check the subject index under Food, Food Industry – Regulation. Be sure to check the paperback supplements to this two volume set as well.

There are also directories that contain information about organizations organized by subject. I found that the most informative organization directory was the Encyclopedia of Associations:

Encyclopedia of Associations

Eds. Christine Maurer and Tara E. Sheets
Detroit, MI: Gale Publishing Co.
LC Call#: REF AS22.E5

Summary:

The name and keyword index for this three-volume set is located in the back of the third volume. The most relevant subject heading is “Food,” however be sure to check “Nutrition” to find organizations devoted to nutrition in general. The encyclopedia is divided into sections, and I found that the most relevant sections was the “Legal, Government, Public Administration, and Military Organization” section, subheading “Food and Drugs” (p. 555). This section contains organizations devoted to foods and drugs in particular. I like this directory a lot because it provides website addresses in addition to the other information.

Three of the most relevant organizations listed in the Encyclopedia of Organizations are:

The Food and Drug Law Institute
1000 Vermont Avenue, NW, Suite 200
Washington, DC 20005-4903
(202) 371-4120

Description:

This non-profit organization is designed to provide a neutral forum in which to examine the laws, regulations, and policies related to foods and drugs.

Association of Food and Drug Officials
P.O. Box 3425
York, PA 17402
(717) 757-2888

<http://www.foodsafety.org/afdo/>

Description:

This organization is designed to foster cooperation between industry and regulators and to promote the enforcement of uniform food and drug laws at all levels of government. Its goal is to provide consumer protection in the most cost-effective way possible.

The Food and Nutrition Board
2101 Constitution Avenue NW
Washington, DC 20418
(202) 334-1732
No website available

Description:

This organization evaluates and advises the federal government on the relationship between food consumption and nutrition and individual health.

The Encyclopedia of Associations is available on-line on Westlaw as EOA and on Lexis in the BUSREF library; ENASSC file. In addition to the Encyclopedia of Associations, the researcher can also consult the Law and Legal Information Directory to find relevant organizations:

The Law and Legal Information Directory
10th Edition

Eds. Steven Wasserman, Jacqueline Wasserman Monroe, and Bonnie Shaw Pfaff

Detroit, MI: Gale Publishing Co.
LC Call #: REF DESK KF 190.L35
Summary:

This source provides more general, all-purpose information, and I did not find it as helpful for finding organizations. It does contain some relevant information about the FDA in its "Federal Regulatory Agencies" section, p. 196. However, I would recommend the Encyclopedia of Associations over this source for the researcher who wants to find relevant organizations.

The following directories specifically provide information about federal agencies:

U.S. Government Manual
Washington, DC: Government Printing Office
LC Call#: REF DESK JK 421.A3
Description:

The FDA is listed in this book in the Department of Health and Human Services section. The names of all relevant FDA officials are listed on p. 267, and pps. 279-282 contain a general description of the FDA, as well as a break-down of its individual divisions.

The U.S. Government Manual is available on in the internet at the GPO Access site (<http://www.access.gpo.gov>), on Westlaw as US-GOVMAN and on Lexis in the BUSREF library; USGM file.

Federal Regulatory Directory
9th Edition

Washington, DC: Congressional Quarterly Publishing

LC Call#: REF KF 5406.A15 F4
Description:

This directory contains the most complete information about the FDA (pps. 205-228). Specifically, it contains small summaries of relevant legislation, telephone contacts lists for individual subjects, and lists of some relevant non-governmental agencies.

Federal Yellow Book

New York, NY: Leadership Directories
LC Call#: REF DESK JK 6.F45

Description:

Relevant FDA listings are found on p. II-255. This directory contains only the relevant contact information and no abstract information.

The Federal Yellow Book is available on Westlaw as FEDYB and on Lexis in the BUSREF library; YBFED file.

To gain biographical information about people in regulatory agencies, I suggest using the PEOPLE library; WPBIO file on Lexis. This is the Washington Post biography file, which contains selected full-text biographical stories from 1989. I suggest doing a simple search for HEADLINE (FDA) to retrieve relevant biographies about FDA officials. Lexis also has a similar New York Times biography file found in the PEOPLE library; GOVBIO file.

In addition to these sources, a very good source for finding people with relevant knowledge is to check the "For Further Information Contact" section of the Federal Register for any regulation.

Finding Relevant Lawyers

The following sources should be consulted in order to find relevant food and drug lawyers:

West's Legal Directory

This source is available on-line only, on the internet (<http://www.wld.com>) and on Westlaw as WLD. Because this service is available on the internet, there is really no reason to use the Westlaw version.

This is a better source for finding Food and Drug lawyers because the user can enter Health in the "Practi

Martindale-Hubbell

New York: Martindale-Hubbell
LC Call#: REF KF 190.M3

Also available on the internet (<http://www.martindale.com>) and on Lexis in the MARHUB library, as well as on CD-Rom.

Comments:

Again, the internet version should be selected over the Lexis version.

Finding food and drug lawyers on the internet version is a challenge. There is no one category for food and drug lawyers, and the relevant subcategories are scattered (e.g. products liability category includes food products liability lawyers). The one redeeming aspect of this service is that the search option for government lawyers yields all the FDA lawyers if "FDA" is placed on the agency field. This source contains free and paid listings.

Litigation Materials

Litigation materials can be helpful, practical resources. They are found both in print and on-line and include a variety of resources such as verdicts and settlements, dockets, jury materials, complaints, briefs, and motions. In addition to court cases, these materials provide the practicing attorney or student with useful information about litigation in a focused practice area. There is not an abundance of litigation material that is helpful to the researcher of the regulation of dietary supplements and the DSHEA, however the material that does exist can be extremely specific and focused.

Finding On-Line Litigation Materials

The Internet can potentially contain a wealth of litigation materials such as motions, briefs, complaints, and docket information. For the researcher interested in a particular court's docket, a good first step is to consult that court's internet site if available. For the legal researcher interested in court documents such as motions and briefs, a good first step is to consult an advocacy organization's website. There are literally hundreds advocacy organizations on the internet concerned with the regulation of dietary supplements, however none have posted any potentially relevant court documents at this point. This vast resource should be consulted for future research.

Of the litigation materials, briefs can be particularly useful for the legal researcher. They contain relevant cases and statutes, and a great deal of work is already done for the legal researcher in a brief. The following database on Lexis can be used to find briefs:

LITGAT library; BRREP file (Brief Reporter)
LITGAT library; BRIEFS file (US Supreme Court Briefs)

The broad search for "dietary supplement" was the most effective search and did not over-retrieve documents in these databases.

Because there are no current Supreme Court cases that address the regulation of dietary supplements, the US Supreme Court Briefs file is not useful at this time. However, the Brief Reporter file did contain the

following highly relevant brief:

Plaintiffs-Appellants' Brief
Nutritional Health Alliance v. Shalala
Second Circuit, November 1997
Summary:

This brief for one of the leading regulation of dietary supplement cases is full of highly relevant information. The brief argues that the prior approval requirement for dietary supplements in the NLEA constitutes an un-Constitutional prior constraint. More importantly, however, the brief contains a Table of Authorities that lists all relevant cases, statutes, and rules and regulations.

Finding Print Litigation Materials

The two major sources for print litigation materials are AmJur Trials and AmJur Proof of Facts:

American Jurisprudence Trials
Bancroft-Whitney/Lawyers Co-Op (1964-); West Group (1996-)
LC Call# KF 8915.A74

American Jurisprudence Proof of Facts 2nd
Bancroft-Whitney/Lawyer's Co-op (1988-); West Group (1996-)
LC Call# KF 8933.A42 1988

In order to find relevant materials from both of the sources, the researcher should consult the most recent multi-volume General Index. The relevant headings of Food and Drugs contained no relevant sub-headings. Instead, there is scattered information about the regulation of dietary supplements found in the References sections of a number of related sub-topics. The following sections had the best citations to relevant periodical articles on the topic of FDA regulation of dietary supplements:

"Drug Products Liability and Malpractice Cases"
Paul D. Reingold

17 AmJur Trials 1
Relevant pps. 10-11 of Pocket Part

Summary:

This article is focused primarily on methods for challenging the FDA's approval of a new drug, however, the Legal and Medical References section did have two citations to potentially relevant periodical articles.

"Food Seizure Litigation"

Marion A. Hoy

9 AmJur Trials 59

Relevant p. 26 of Pocket Part

Summary:

This article contains detailed information about litigation strategies regarding food seizures and the FDA policy on food seizure. While this is not necessarily relevant to the regulation of dietary supplements, the Legal References section has a few good citations to potentially relevant secondary articles.

"Negligent Use of Diet and Weight Control Drugs in the Treatment of Obesity"

David R. Gee, LLB

23 AmJur Proof of Facts 2d 293

Relevant pps. 57-58 of Pocket Part

This article is primarily focused on the use of drugs to treat obesity (not dietary supplements), however the Legal and Medical References section contains one potentially relevant citation to an article about the regulation of dietary supplements.

Effectiveness of Print Research and Availability of Print Sources On-Line

Researching the print resources is a very tedious process since there are no relevant sections and many potentially relevant citations in other sections. A better alternative for the legal researcher would be to use the on-line versions of [AmJur Trials](#) and [AmJur Proof of Facts](#) if possible. These sources have recently become available on Westlaw in the following databases:

AMJUR-TRIALS – [AmJur Trials](#)

AMJUR-POF – [AmJur Proof of Fact](#)

A broad keyword search is effective in these databases because the information about dietary supplements is relatively sparse. I recommend the following search queries:

FDA /p "dietary supplement"
"dietary supplement"

Verdicts and Settlements

There are several on-line resources available for finding verdicts and settlement. The Court TV website (<http://www.courtstv.com>) often has useful information about the verdicts and settlements of more prominent cases. This website contained no pertinent information for the topic of dietary supplement regulation.

The following databases on Lexis and Westlaw also have information on verdicts and settlement:

Lexis:

LITGAT library; ALLVER file – Jury Verdicts and Settlement Combined

LITGAT library; NTLREV – National Jury Verdict Review and Analysis

Westlaw:

VST – Verdicts, Settlements, and Tactics file

VST had no relevant verdicts or settlements, however the Lexis file NTLREV was slightly more useful. It had information on one relevant settlement and one relevant verdict concerning plaintiffs injured by dietary supplements. Lexis seems to have broader resources for researching in this area.

Trial Transcripts

There are currently no trial transcripts available on-line pertaining to litigation about the regulation of dietary supplements. For future research in this area, the researcher should consult the following databases:

Lexis:

LITGAT library; TRSRCH (Michie Trial Search)

Westlaw:

Notable Trials file – has transcripts of famous trials

Westlaw and Lexis Litigation Guides

Westlaw and Lexis do have relevant litigation guides, and I have explained them fully under the Looseleaf Services portion of this research guide.

Books, CLE Materials, And Dissertations

Books

How to Begin Book Research

The best place to begin researching books is at your local institution. From there, a researcher can expand outward to regional consortiums and larger library databases. Additionally, there is a limited array of databases on-line that will provide a researcher with book titles, continuing education materials, and dissertations. I have provided information about all of these research sites below.

Library of Congress Subject Headings

A good first step for a researcher is to find the relevant subject headings found in Library of Congress Subject Headings.

Library of Congress Subject Headings
Washington, DC: Library of Congress
1998

Page numbers vary, check subject index in the back.

For the regulation of dietary supplements, I found the following to be by far the most useful headings:

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Note: this subject heading is used for dietary supplements, food supplements, and nutritional supplements, so the researcher need not try these alternatives when doing a subject search.

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Other possibilities are:

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Tools for Researching and Formulating Search Terms

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Effectiveness of Book Research

Unfortunately, books are not the most effective source for searching the latest regulation of dietary supplements. There are books covering the broad topic of dietary supplements, but all tend to be focused only on the medical/nutritional side of the issue and not on the legal/regulatory side of the issue. (I do, however, recognize that the good researcher should get an adequate background on the nutritional aspects of dietary supplements. See the entry Dietary Supplements : Use and Regulation below.) Additionally, there are books on the FDA in general, but none address the regulation of dietary supplements in any noteworthy fashion.

The following sources are what I consider to be the best books on the regulation of dietary supplements, listed from most to least informative.

Dietary Supplement Health and Education Act: A Legislative History and
Analysis

I. Scott Bass and Anthony L. Young

Washington, DC: Food and Drug Law Institute

1996

319 pps.

Summary:

This is the most complete book on the regulation of dietary supplements after the DSHEA. It summarizes the DSHEA, provides a brief history of dietary supplement regulation, and describes the passage of the Act. Most importantly, it provides the full-text of the DSHEA and related legislation (including the NLEA and Dietary Supplement Act of 1992), as well as relevant committee reports, Congressional Record excerpts of floor debate and other legislative history documents. It also contains some of the most important agency documents from the Federal Register.

Both authors of this book are practicing food and drug attorneys. Mr. Bass in particular served as Chair of the Section on Food, Drug and Cosmetic Law of the New York State Bar. He is also an adjunct professor at the Georgetown University Graduate School of Public Policy.

Dietary Supplements: Use and Regulation

Donna v. Porter

Washington, DC: Congressional Research Service, Library of Congress

March 4, 1994

43 pps.

Summary:

This publication is particularly useful because it gives detailed information about the legislation pending just prior to the passage of the DSHEA (including the DSHEA) and provides an enormous amount of statistics, charts, and graphs describing the scientific and nutritional side of dietary supplements. This is an ideal source for the researcher to gain a background on the definition and function of dietary supplements without going into the scientific detail characteristic of most other books on the topic. The author is the Specialist in Life Sciences, Science Policy Research Division.

Dietary Supplements: Bills in the 103rd Congress

Donna V. Porter

Washington, DC: Congressional Research Service, Library of Congress

January 28, 1994

15 pps.

Summary:

This article examines all relevant bills in the 103rd Congress, comments on the bills' purposes, and describes what happened to the bill. There is a nice summary of the article at the beginning. The article could be organized more efficiently as the bills seem to be discussed in random order.

The Practical Guide to Food and Drug Law and Regulation

Eds. Kenneth R. Pina, Rhone Poulonc Rorer and Wayne L. Pines

Washington DC: The Food and Drug Law Institute

1998

350 pps.

Summary:

This book gives a broad overview of FDA policy and provides practical guidelines concerning the contours of FDA regulation. The section on Regulation of Food and Food Additives is particularly helpful for the dietary supplement researcher. This book is not widely distributed, however, selected pages can be viewed at the Food and Drug Law Institute website at <http://www.fdli.org/Publications.html>. The content of the book is extremely thorough and the information is very current.

Handbook of Federal Drug Law

James Robert Nielsen

Philadelphia: Lea and Fibiger

1992

206 pps.

Summary:

While this book focuses primarily on drug regulation, it is useful to the legal researcher for two reasons. First, a dietary supplement is defined as something between a food and a drug, so it is useful to be familiar with the elements of a "drug" to be able to analyze controversial rulings about whether a specific supplement is a food or drug. Second, its chapter on labeling is very comprehensive and is a good place to get a background on the general laws governing dietary supplement labeling as it relates to other labeling issues.

Fundamentals of Law and Regulation: An In-Depth Look at Foods, Veterinary Medicines, and CosmeticsC

Eds. Robert P. Brady, Richard M. Cooper, and Richard S. Silverman

Washington, DC: The Food and Drug Law Institute

1997

Vol. 1, pps. 257-284

Summary:

This relevant chapter contains a somewhat in-depth treatment of the history of dietary supplements, the DSHEA, and the philosophy behind dietary supplement regulation. Specifically, it explains definitions in the DSHEA, advertising claims, and describes the interaction between the DSHEA and the NLEA.

Continuing Legal Education (CLE) Materials

Effectiveness of Using CLE Materials

CLE Materials provide a lot of information to the researcher who has an interest in very specific aspects of the regulation of dietary supplements. Additionally, they provide practical guidance relating to the topic.

Research Sources and Search Formulation

The two best sources for accessing CLE materials related to this topic are the following on-line databases of Westlaw:

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PLI-LIT was not a useful source in this case. I found that the best search in both databases was “dietary /s supplement.” (I did not find using the synonyms to dietary helpful here.) Additionally, there are state-specific databases on-line. These databases are not very helpful to the legal researcher interested in the federal side of the issue.

On Lexis, the researcher can search the databases published by the American Bar Association, American Law Institute, and Practising Law Institute by accessing the CLE library; ALIABA, ABALIT, or ALLPLI files, among others.

Best CLE Materials:

The following CLE materials are the most topical and the most current CLE materials relating to the regulation of dietary supplements.

Prior Restraints

Floyd Abrams

Patents, Copyright, Trademarks and Literary Property Course Handbook Series

The Practicing Law Institute

November 1998

540 PLI/Pat 861

Relevant page: p. 1131

Summary:

This practice guide provides useful information to the researcher interested in the constitutional dimension of dietary supplement labeling. The Procedural Safeguard section contains a small but important section on pertinent cases relating to dietary supplement regulation and prior restraint. This source is a good starting point for the researcher particularly interested in this aspect of the issue, because it provides a broad picture of where dietary supplement regulation fits in to the overall debate surrounding prior restraint.

Summary of Major 1998 Commercial Speech Developments

P. Cameron DeVore

Patents, Copyright, Trademarks and Literary Property Course Handbook Series

The Practicing Law Institute

November 1998

538 PLI/Pat 7

Relevant pages: pps. 9-10

Summary:

This source has a small section describing various first amendment challenges to dietary supplement regulation, and it specifically lists cases and statutory citations. It also discusses briefly the FDA's role in the issue. It would be a great starting point for a researcher interested in the industry's side of the issue. The weakness with this particular source is that it is indexed by court, and not by topic. A topical index could more easily lead the researcher the pertinent dietary supplement section.

Federal Trade Commission Advertising Enforcement

Joel Winston
Corporate Law and Practice Course Handbook Series
The Practicing Law Institute
October 1998
1076 PLI/Corp 97
Relevant pages: pps. 103, 106, 115-117

Summary:

This is a very good source if the researcher is interested in the relationship between the FDA's regulation of dietary supplements and the FTC's regulation of dietary supplements. This article briefly describes the interaction between the two agencies and briefly discusses the roles of each. The article is focused primarily on issues of enforcement of advertising regulations, and is organized by topic. Like the other sources, it lists specific primary resources including cases.

Advertising and Unfair Competition

Terry Calvani (Pillsbury, Madison & Sutro,
Washington, D.C.)
American Law Institute – American Bar Association Continuing Legal Education
March 19, 1998
SB75-ALI-ABA 109
Relevant pages: pps. 117, 128

Summary:

The Health and Safety Claims section discusses briefly the role of the FDA and FTC under the Health and Education Act of 1994. The article also generally discusses the differences between the roles of the FDA and the FTC in the regulation of dietary supplements, with an emphasis primarily on the FTC.

Dissertations

I was unable to find any relevant dissertations on the topic of regulation of dietary supplements. For the researcher who wants to update this research guide's findings with regard to dissertations, the best source is the following database on Westlaw:

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Bibliographies

Bibliographies are a very good time-saving tool because the research is already done for the researcher. Bibliographies can be books in themselves, or they can be contained within a book or legal periodical article.

Books that are Bibliographies

The best way to find books that are bibliographies is look for the “–bibliography” subdivision in your search results. Books that are bibliographies are found in the same way books are found. There are no such books on the regulation of dietary supplement topic area. There are book bibliographies that deal with the broader topic of FDA regulation, as well as bibliographies that deal with the nutritional/medical side of dietary supplements. These bibliographies are not particularly helpful to the researcher looking for the narrow topic of regulation of dietary supplements, and most are outdated. However, one source might be useful for the researcher who needs a very broad background on the FDA:

The United States Food and Drug Administration: Purpose, History, and Function

Janice Dee Gilbert
Vance Bibliographies, Monticello, Illinois
April 1982
13 pps.

This bibliography contains pertinent entries on food additives and vitamins and provides information on the complexity of issues controlled by the FDA. While this source is very outdated, it is useful for the researcher looking for a broad overview of the FDA and its regulation policies. The bibliography is not indexed, but is relatively short enough be manageable w/o an index. The bibliography is also not annotated, which would be an obvious way to improve the usefulness of the bibliography.

Bibliographies within Books

Bibliographies within books can be found by looking in the notes field in the long display on Hollis and by looking for similar information in the on-line catalogs. Unfortunately, none of the most relevant books contained separate bibliography sections. My best suggestion is to examine the footnotes within the law review articles I cited in the “Periodicals” section of this guide. They will lead the researcher to other relevant primary and secondary material.

Legal Encyclopedias

Generally, legal encyclopedias are not helpful for researching the regulation of dietary supplements. However, for future research, consult the following two legal encyclopedias in print:

American Jurisprudence 2nd:

American Jurisprudence, Second Edition

Lonnie E. Griffith, Jr., ed.

Rochester, NY: Lawyers Cooperative Publishing (1990-)

LC Call#: KF 154.A42

Updated by Cumulative Pocket Part Supplement

To search in American Jurisprudence 2nd, consult the multi-volume general index. Headings that could potentially be relevant for future research include:

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American Jurisprudence 2nd is also available on-line on Lexis (2NDARY library; AMJUR file) and Westlaw (AMJUR). Ordinarily, it is best to conduct a natural language search in these databases. However, because the information on dietary supplements is so sparse, a term search for “dietary supplement” is just as effective. I conducted a search for “dietary supplement” and found only tangentially relevant articles that were also

cited in AmJur Trials. Considering the abundance of other good sources for finding relevant secondary material, this legal encyclopedia is not all that helpful.

Corpus Juris Secundum

Corpus Juris Secundum

St. Paul, MN: West Publishing (1936-)
LC Call#: KF 154.C56
Updated Annually By Cumulative Annual Pocket Part Supplement

To search in Corpus Juris Secundum, use the multi-volume index. The following subjects could be relevant for future research:

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Corpus Juris Secundum is only available in print and is no more useful than American Jurisprudence 2nd.

Conclusion

As this research guide indicates, there is a vast amount of resources available for this topic. In general, on-line sources are easier to use than print sources and tend to be more effective for finding crucial current information. I have indicated within the guide the few instances in which the print sources seem to be more effective (e.g. looseleaf services). Since this guide is written for student researchers, access to these on-line sources will most likely be abundant.

Term searching also seems to be effective for this type of research; however, in a few instances I have indicated a preference for subject searching. Generally the subject searching method is a good way to ensure that all relevant materials that do not use the common term “dietary supplement” are retrieved. Term searching is particularly effective for this topic because “dietary supplement” is a term in itself and also appears within the common name of the DSHEA.

Finally, I have tried to indicate what the best sources are in each genre by including them at the beginning of the genre and/or indicating my preference in the description of the source. I have also tried to provide guidance to future researchers by explaining how to update relevant sources and by describing potentially relevant sources. Hopefully, with the research information and tips contained within this guide, future legal researchers will be able to successfully navigate through the abundance of relevant materials.